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Warner Chilcott Company, LLC
and Warner Chilcott (US), LLC.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

WARNER CHILCOTT COMPANY, LLC and WARNER CHILCOTT (US), LLC, Plaintiffs, v. TEVA PHARMACEUTICALS USA, INC. and TEVA PHARMACEUTICAL INDUSTRIES LTD., Defendants.	CIVIL ACTION NO.

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Warner Chilcott Company, LLC and Warner Chilcott (US), LLC, by their undersigned attorneys, bring this action against Defendants Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd. (collectively "Teva"), and hereby allege as follows:

THE PARTIES

1. Plaintiff Warner Chilcott Company, LLC ("WCCL"), is a limited liability company organized and existing under the laws of Puerto Rico, having offices at Union Street, Road 195, Km. 1.1, Fajardo, Puerto Rico.

2. Plaintiff Warner Chilcott (US), LLC ("WCUS") is a limited liability company established under the laws of the state of Delaware with offices at 100 Enterprise Drive, Rockaway, NJ 07866. WCCL and WCUS hereinafter are referred to collectively as "Warner Chilcott."

3. Upon information and belief, Defendant Teva Pharmaceuticals USA, Inc. ("Teva USA") is a Delaware corporation with its principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454.

4. Upon information and belief, Teva USA is in the business of, among other things, formulating, developing, manufacturing, marketing and selling generic copies of branded pharmaceutical products for the U.S. market, including in New Jersey.

5. Upon information and belief, Defendant Teva Pharmaceutical Industries Ltd. ("Teva Ltd.") is a company organized and existing under the laws of Israel having its principal place of business at 5 Basel Street, Petach Tikva 49131, Israel.

6. Upon information and belief, Teva Ltd. is in the business of developing, manufacturing, marketing, and selling pharmaceutical products, including generic

pharmaceutical products, throughout the United States, including in this judicial district, through the actions of its agents and operating subsidiaries, including Teva USA.

7. Upon information and belief, Teva USA is a wholly-owned subsidiary of Teva Ltd.

JURISDICTION AND VENUE

8. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

9. Upon information and belief, this Court has personal jurisdiction over Teva USA and Teva Ltd. because, *inter alia,* they have committed, aided, abetted, actively induced, contributed to or participated in the commission of a tortious act of patent infringement leading to foreseeable harm and injury to Warner Chilcott, namely, the submission to the U.S. Food and Drug Administration ("FDA") of the Abbreviated New Drug Application ("ANDA") at issue in this case.

10. Upon information and belief, this Court has personal jurisdiction over Teva USA and Teva Ltd. because, *inter alia,* they have purposefully availed themselves of the benefits and protections of New Jersey's laws such that they should reasonably anticipate being haled into court here. Upon information and belief, Teva USA and Teva Ltd. have had persistent, continuous and systematic contacts with this judicial district, including, *inter alia,* maintaining offices in New Jersey and, either directly or through an agent, deriving substantial revenue from the development, manufacture and/or sale of pharmaceutical products that are sold in New Jersey.

11. Upon information and belief, Teva USA conducts business in New Jersey and has offices and facilities in New Jersey. Upon information and belief, Teva USA is registered to do

business in New Jersey and has appointed a registered agent in New Jersey for the receipt of service of process.

12. Teva USA and Teva Ltd. are agents of each other with respect to the development, regulatory approval, marketing, sale and distribution of generic pharmaceutical products, including the generic risedronate sodium delayed release tablets described in ANDA No. 20-3217 ("Teva's ANDA product").

13. Upon information and belief, Teva USA's preparation and submission of Teva's ANDA was done collaboratively with, and at least in part for the benefit of Teva Ltd.

14. If ANDA No. 20-3217 is approved, Teva's ANDA product which is charged with infringing the patents-in-suit, would, among other things, be marketed and distributed in New Jersey, prescribed by physicians practicing in New Jersey and dispensed by pharmacies located within New Jersey, all of which would have a substantial effect on New Jersey.

15. Upon information and belief, Teva USA and Teva Ltd. have jointly filed numerous complaints in New Jersey, including patent infringement cases, and therefore have submitted to the jurisdiction of this Court and availed themselves of the laws and protections of New Jersey.

16. Accordingly, this Court has personal jurisdiction over the Defendants because they, either directly or through an agent, including each other, regularly do or solicit business in New Jersey, engage in other persistent courses of conduct in New Jersey, and derive substantial revenue from services, or things used or consumed in New Jersey.

17. Venue is proper in this Court under 28 U.S.C. §§ 1391(b) and (c) and 28 U.S.C. § 1400(b).

BACKGROUND

18. Warner Chilcott is the holder of New Drug Application ("NDA") No. 22-560, which relates to delayed release oral tablets with 35 mg of the active ingredient risedronate sodium. These tablets were approved by the FDA on October 8, 2010. The tablets are sold under the trademark Atelvia™ and are indicated for the treatment of osteoporosis in post-menopausal women.

19. U. S. Patent No. 7,645,459 ("the '459 patent") entitled "Dosage Forms of Bisphosphonates" lawfully issued from the United States Patent and Trademark Office ("PTO") on January 12, 2010. A copy of the '459 patent is attached as Exhibit A.

20. U. S. Patent No. 7,645,460 ("the '460 patent") entitled "Dosage Forms of Risedronate" lawfully issued from the United States Patent and Trademark Office ("PTO") on January 12, 2010. A copy of the '460 patent is attached as Exhibit B.

21. Warner Chilcott Company, LLC owns the '459 and '460 patents.

22. The '459 and the '460 patents cover the use of Atelvia™ in accordance with the labeling approved by the FDA and have been listed in the FDA *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") for that product.

23. Upon information and belief, Teva USA, jointly with, and/or as the agent of, Teva Ltd. submitted Teva's ANDA to the FDA under 21 U.S.C. § 355(j), in order to obtain approval to engage in the commercial manufacture, use or sale of a generic version of Atelvia™ prior to the expiration of the '459 and '460 patents.

COUNT I
CLAIM FOR INFRINGEMENT OF THE '459 PATENT

24. Paragraphs 1 through 23 are repeated.

25. Upon information and belief, Teva's ANDA No. 20-3217 included a certification with respect to the '459 patent under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the '459 patent is invalid, unenforceable and/or will not be infringed by the manufacture, use or sale of Teva's ANDA product.

26. Upon information and belief, Teva USA sent notice of that certification to Warner Chilcott on or about October 13, 2011. Warner Chilcott received that notification on or about October 14, 2011.

27. Because Teva's ANDA was submitted under 21 U.S.C. § 355(j), in order to obtain approval from the FDA to engage in the commercial manufacture, use or sale of a drug product claimed in the '459 patent before its expiration, Teva USA, jointly with, and/or as the agent of Teva Ltd., has committed an act of infringement pursuant to 35 U.S.C. § 271(e)(2)(A).

28. Teva USA was acting jointly with Teva Ltd. and/or acting as the agent of Teva Ltd. when it submitted Teva's ANDA to the FDA. By acting jointly with Teva USA to submit the application, and/or causing its agent to submit the application, Teva Ltd. committed an act of infringement with respect to the '459 patent under 35 U.S.C. § 271(e)(2)(A).

29. The commercial manufacture, use, offer for sale, sale and/or importation of Teva's ANDA product before the expiration of the '459 patent will infringe one or more claims of the '459 patent.

30. Warner Chilcott is entitled to relief provided by 35 U.S.C. § 271(e)(4), including an order from this Court that the effective date of the approval of Teva's ANDA be a date that is not earlier than the expiration date of the '459 patent, or any later expiration of exclusivity for the '459 patent to which Warner Chilcott is or becomes entitled.

31. Teva's certification to the FDA that the '459 patent was not infringed, invalid and/or unenforceable was baseless, and therefore this case is exceptional under 35 U.S.C. § 285. Warner Chilcott is entitled to its costs and reasonable attorney fees.

COUNT II
CLAIM FOR INFRINGEMENT OF THE '460 PATENT

32. Paragraphs 1 through 23 are repeated.

33. Upon information and belief, Teva's ANDA No. 20-3217 included a certification with respect to the '460 patent under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the '460 patent is invalid, unenforceable and/or will not be infringed by the manufacture, use or sale of Teva's ANDA product.

34. Upon information and belief, Teva USA sent notice of that certification to Warner Chilcott on or about October 13, 2011. Warner Chilcott received that notification on or about October 14, 2011.

35. Because Teva's ANDA was submitted under 21 U.S.C. § 355(j), in order to obtain approval from the FDA to engage in the commercial manufacture, use or sale of a drug product claimed in the '460 patent before its expiration, Teva USA, jointly with, and/or as the agent of Teva Ltd., has committed an act of infringement pursuant to 35 U.S.C. § 271(e)(2)(A).

36. Teva USA was acting jointly with Teva Ltd. and/or acting as the agent of Teva Ltd. when it submitted Teva's ANDA to the FDA. By acting jointly with Teva USA to submit the application, and/or causing its agent to submit the application, Teva Ltd. committed an act of infringement with respect to the '460 patent under 35 U.S.C. § 271(e)(2)(A).

37. The commercial manufacture, use, offer for sale, sale and/or importation of Teva's ANDA product before the expiration of the '460 patent will infringe one or more claims of the '460 patent.

38. Warner Chilcott is entitled to relief provided by 35 U.S.C. § 271(e)(4), including an order from this Court that the effective date of the approval of Teva's ANDA be a date that is not earlier than the expiration date of the '460 patent, or any later expiration of exclusivity for the '460 patent to which Warner Chilcott is or becomes entitled.

39. Teva's certification to the FDA that the '460 patent was not infringed, invalid and/or unenforceable was baseless, and therefore this case is exceptional under 35 U.S.C. § 285. Warner Chilcott is entitled to its costs and reasonable attorney fees.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

(a) Judgment that each of the Defendants has infringed one or more claims of the '459 patent by submitting ANDA No. 20-3217.

(b) A permanent injunction be issued, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining the Defendants, their officers, agents, attorneys, and employees, and those acting in privity or concert with them, and their successors and assigns, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of compositions as claimed in the '459 patent;

(c) Judgment that each of the Defendants has infringed one or more claims of the '460 patent by submitting ANDA No. 20-3217.

(d) A permanent injunction be issued, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining the Defendants, their officers, agents, attorneys, and employees, and those acting in privity or concert with them, and their successors and assigns, from engaging in

the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of compositions as claimed in the '460 Patent;

(e) An order be issued pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any approval of ANDA No. 20-3217 be a date that is not earlier than the expiration of the '459 and '460 patents, or any later expiration of exclusivity for the '459 and '460 patents to which Plaintiffs are or become entitled; and

(f) Declaring this to be an exceptional case and awarding Plaintiffs their attorney fees under 35 U.S.C. § 285.

(g) Such other and further relief as the Court may deem just and proper.

Dated: November 22, 2011

Respectfully submitted,

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CERTIFICATION PURSUANT TO L. CIV. R. 11.2

Plaintiffs, by their undersigned counsel, hereby certify pursuant to L. Civ. R. 11.2 that the matter in controversy is the subject of WARNER CHILCOTT COMPANY, LLC and WARNER CHILCOTT (US), LLC v. WATSON PHARMACEUTICALS, INC., WATSON LABORATORIES, INC. – FLORIDA, and WATSON PHARMA, INC., Civil Action 2:11−CV−05989−FSH−PS (D.N.J.)(the "Watson case"). The Watson case involves the same patents and the same product as the matter in controversy.

Dated: November 22, 2011

Respectfully submitted,

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